SECTIONS OF FEDERAL FOOD, DRUG, AND COSMETIC ACT INVOLVED IN VIOLATIONS REPORTED IN D.D.N.J. 5781-5820

Adulteration, Section 501(b), the article purported to be and was represented as a drug, the name of which is recognized in an official compendium (United States Pharmacopoeia), and its strength differed from, and its quality and purity fell below, the standard set forth in such compendium; Section 501(c), the article was not subject to the provisions of Section 501(b), and its strength differed from, or its purity or quality fell below, that which it purported or was represented to possess; and Section 501(d)(2), the article was a drug, and a substance had been substituted wholly or in part therefor.

Misbranding, Section 502(a), the labeling of the article was false and misleading; Section 502(b), the article was in package form, and it failed to bear a label containing (1) the name and place of business of the manufacturer, packer, or distributor, and (2) an accurate statement of the quantity of contents; Section 502(d), the article contained a chemical derivative of codeine, and its label failed to bear the name, and quantity of such derivative and in juxtaposition therewith the statement "Warning-May be habit forming"; Section 502(e), the article was a drug not designated solely by a name recognized in an official compendium, and its label failed to bear (1) the common or usual name of the drug; and (2) the drug was fabricated from two or more ingredients, and its label failed to bear the common or usual name of each active ingredient: Section 502(f), the labeling of the article failed to bear (1) adequate directions for use and (2) adequate warnings against use in those pathological conditions, or by children, where its use may be dangerous to health, or against unsafe dosage or methods of duration of administration or application, in such manner and form, as are necessary for the protection of users; Section 502(g), the article purported to be a drug, the name of which is recognized in an official compendium (United States Pharmacopeia), and it was not packaged as prescribed therein; and Section 502(i)(3), the article was a drug offered for sale under the name of another drug.

## DRUGS AND DEVICES ACTIONABLE BECAUSE OF FAILURE TO BEAR ADEQUATE DIRECTIONS OR WARNING STATEMENTS

5781. Hoxsey treatment for internal cancer. (Inj. No. 311.) Supplement to D.D.N.J. No. 5202.

PETITION FILED: On 10-6-58, a petition for an order to show cause in criminal contempt was filed in the Western District of Pennsylvania, against Hoxsey Cancer Clinic, a corporation, Portage, Pa., and John J. Haluska, Samuel J. Einhorn, John H. Benko, Harold F. Galbraith, A. A. Nelson, and Harry A. Stegman, incorporators, directors, and trustees of the clinic.

Disposition: On 10-30-58, the following supplemental consent decree was entered:

MILLER, District Judge: "AND NOW, to wit, this 30th day of October, 1958, the United States of America having filed a petition for order to show cause why the defendants should not be punished for criminal contempt of this Court's permanent injunction, which became effective November 1, 1957, and the Court being convinced that the terms of this supplemental decree and the provisions thereof are necessary to effectuate the operation of this Court's orders and decrees, and the defendants having expressed to the Court a willingness to dissolve the corporation and to wind up its business of delivering medicine to persons at Portage, Pennsylvania, and having consented to this supplemental consent decree;